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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,569	02/21/2002	Gholam-Reza Zadno-Azizi	38349-0102D	4156

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EXAMINER

CHATTOPADHYAY, URM1

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

JP

Office Action Summary	Application No. 10/081,569	Applicant(s) ZADNO-AZIZI ET AL.	
	Examiner Urmi Chattopadhyay	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2005 and 31 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 January 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>9/20/04; 10/27/04; 12/6/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The Supplemental Amendment filed 2/24/05 and Response to Notice of Non-Compliant Amendment filed 5/31/05 have been entered. The request for interference has been withdrawn. Claims 16-19 have been canceled and new claims 28-31 have been added. All pending claims are being considered for further examination on the merits, which are claims 20-31.

Information Disclosure Statement

2. The information disclosure statements (IDSs) filed on 9/20/04, 10/27/04 (same as IDS filed on 4/23/03) and 12/6/04 have been considered by the examiner. An initialed and signed copy of each PTO-1449 is enclosed herewith.

Claim Objections

3. Claim 30 objected to because of the following informalities: it appears that --system-- should be inserted after device in line 1 for preamble consistency. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claim 27 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 27 requires that the one-way valve be guidable on the elongate passage and that the frame self-expands. There is no support for this combination of limitations in the specification.

According to page 11, lines 3-11 and Figure 11, the embodiment that includes the one-way valve guidable on an elongate passage has the malleable longitudinal elements of the frame bending beyond their yield point (non-self expanding). According to page 11, lines 12-23 and Figure 12, the embodiment that includes a self-expanding frame (made of a spring material) has the frame being inserted into an outer sheath.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 20-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Andersen et al. (USPN 5,411,552, as cited in applicant's IDS).

Andersen et al. discloses a pulmonic fluid flow control device and system with all the elements of claims 20, 23, 26 and 27. See column 3, lines 44-45 and column 7, lines 12-14 for the fluid-flow control device (9) including a biological valve (6), which is a one-way valve,

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dimensioned for pulmonary placement, wherein the valve is configured to restrict fluid flow.

See Figure 2 and column 5, lines 33-35 for a frame (1) coupled to the valve (6). See column 2, lines 47-52, column 3, lines 44-45, column 4, lines 9-11, column 6, lines 30-33 and Figure 7 for the frame (1) self-expanding within a pulmonic passageway (pulmonary artery) sufficiently to anchor the flow-control device within the pulmonic passageway. See column 2, lines 45-52 for the one-way valve being guidable into an outer sheath (protection cap 11A) for positioning the valve, and column 2, lines 42-45, column 5, lines 40-45 and Figure 3 for the one-way valve being guidable on an elongate passage (balloon 13 of catheter 11) for positioning the valve. See column 6, lines 30-36 and Figure 7 for the device being expanded to a diameter greater than the diameter of the body passageway into which it is implanted. Therefore, blood is prevented from flowing between the outer surface of the device and the interior of the passageway at the points of contact to form a seal therebetween.

Claims 21 and 24, see column 3, lines 44-45 for the valve prosthesis being sized for placement within the pulmonary artery. Since the size of the human pulmonary artery ranges from about 5mm in an infant up to about 35mm in a full sized adult, as evidenced by Ruiz (USPN 5,868,779) and Ruiz (USPN 5,954,765) which were both cited in the office action mailed 4/27/04, the valve of Andersen et al. will have an outer diameter of *approximately* 0.349 inches.

Claims 22 and 25, see Figure 2 for the valve body having a slit (junction between cusps) through which fluid can flow (when opened).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andersen et al. in view of Love (USPN 4,470,157).

Andersen et al. discloses a pulmonic fluid flow control device and system with all the elements of claims 20, 23, 26 and 27, but is silent to the valve being biased into the closed configuration, as required by claims 28 and 30. See column 5, line 29 for the valve (6) being a biological valve, which inherently is movable between an open configuration allowing fluid flow through the valve and a closed configuration restricting flow through the valve. Love teaches applying stitches or clips (20) to bias close the cusps of a heart valve in order to close the valve once the pressure differential, which caused the edges of the cusps to separate for blood to flow through, terminates. Any back pressure will force the edges of the cusps to seal tighter against the edges of adjacent cusps. See Figure 3, column 3, lines 39-49 and column 5, lines 40-44. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Love to modify the valve body of Andersen et al. by biasing the cusps of the valve into the closed configuration in order to close the valve once the pressure differential terminates. Any back pressure will force the edges of the cusps to seal tighter against the edges of adjacent cusps. The examiner contends that this will better guard against valvular regurgitation at any point during pumping of the heart.

Claims 29 and 31, see column 3, lines 44-45 for the valve prosthesis being sized for placement within the pulmonary artery. Since the size of the human pulmonary artery ranges from about 5mm in an infant up to about 35mm in a full sized adult, as evidenced by Ruiz (USPN 5,868,779) and Ruiz (USPN 5,954,765), the valve of Andersen et al. will have an outer diameter of *approximately* 0.349 inches. On page 4, section 12 of the "Declaration of Antony Fields Under 37 C.F.R. 1.132" filed 10/20/03, it is admitted that the sub-branch of a human bronchial passageway can have an average diameter of up to about 9.10 ± 2.05 mm. Because there is an overlapping in size between the pulmonary artery and the bronchial sub-branch, it is obvious that the fluid-flow control device (9) of Andersen et al. sized for use in the pulmonary artery will also be dimensioned to be placed within a bronchial passageway. According to Merriam-Webster Online Dictionary, a definition of "block" is "c : to *hinder* the passage, progress, or accomplishment of by or as if by interposing an obstruction" (italics for emphasis). When the device of Andersen et al., as modified by Love, is placed within a bronchial passageway, the device will indeed *hinder* the passage of air through the bronchial passageway when the valve is in the closed configuration.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

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provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 20-22 and 26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,954,766 (cited in applicant's IDS) in view of Andersen et al. (USPN 5,411,552 as cited in applicant's IDS) and over claims 1 and 7 of U.S. Patent No. 6,632,243 in view of Andersen et al. (USPN 5,411,552 as cited in applicant's IDS). The patents claim a fluid-flow control device comprising a frame, an outer surface configured to seal with an interior of a body passageway and a one-way slit valve coupled to the frame. Andersen et al. teaches the additional limitation of the valve being dimensioned for pulmonary placement in order to, upon implantation in a pulmonary artery suffering from valvular insufficiency, restore uni-directional flow within the pulmonary artery. See column 3, lines 43-46. Andersen et al. also teaches the frame self-expanding to anchor the flow-control device within the passageway. See column 6, lines 30-36. Because the flow-control device of Andersen et al. is sized for placement within the pulmonary artery, it will have a diameter of approximately 0.349 inches. See column 3, lines 44-45.

Response to Arguments

11. Applicant's arguments with respect to claims 20-31 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

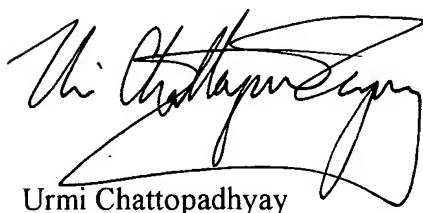
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Urmi Chattopadhyay whose telephone number is (571) 272-4748.

The examiner can normally be reached on Tuesday-Thursday 10:00am - 6:00pm.

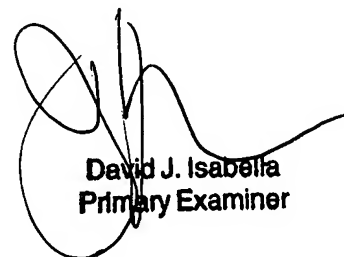
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Urmi Chattopadhyay

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David J. Isabella
Primary Examiner